

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

MDL No. 2327

WAVE 1 CASES ON ATTACHED EXHIBIT A

**PLAINTIFFS' AMENDED MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY
OF THOMAS C. WRIGHT, JR., M.D.**

Pursuant to Federal Rules of Evidence 702, 403, and 104 Plaintiffs in actions listed on attached Exhibit A submit this Amended Memorandum of Law in Support of Their Motion To Exclude the General Opinions and Testimony of Thomas C. Wright, Jr., M.D.

Introduction and Summary

Dr. Wright is a pathologist with no clinical experience in treating women with pelvic organ prolapse (POP). His pathologist opinion can be summarized as: pathology slides cannot correlate to clinical symptomology such as pain and dysfunction. He is not a urologist, gynecologist, or urogynecologist. He has never implanted or explanted any mesh of any type. He does not diagnose or treat female pelvic pain and dysfunction. Despite his lack of relevant clinical experience, Dr. Wright attempts to offer clinical medical opinions in his report regarding the causes of POP, treatment options for POP, and success and failure rates of POP treatment. Dr. Wright is unqualified to offer these opinions and they should be excluded by this Court.

1. The Daubert Standard Requires Qualifications and Methodology That Connect to the Proffered Opinion

The proponent of expert testimony must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed.R.Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

An expert’s opinion and methodology must be reliable and the expert must reliably apply the methodology to the facts of the case. *Id.* at 592-93. Expert witnesses must “employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

“The Supreme Court listed several non-exclusive factors to guide courts in their screening function: whether the proposed evidence or theory ‘can be (and has been) tested’; whether it ‘has been subjected to peer review and publication’; whether it has been evaluated in the light of ‘potential rate[s] of error’; and whether the theory has been accepted in the ‘relevant scientific community.’ *Daubert*, 509 U.S. at 593–94.

Even if the expert is qualified and the testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must “fit” the case, *i.e.* there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

2. Dr. Wright, A Pathologist, Is Unqualified to Offer Opinions Regarding the Causes of POP/SUI, Treatment Options for POP/SUI, and the Success and Failure Rates of POP/SUI Treatment.

Dr. Wright has spent his entire career working in the field of pathology. His only clinical experience treating patients involves performing a procedure called a colposcopy, wherein Dr. Wright examines the cervix with a microscope to identify abnormalities, take biopsies, and treat precancerous conditions. Exhibit B at 6:18-8:11 (Deposition of Thomas C. Wright, Jr., M.D.). Dr. Wright's clinical experience is confined and limited to coloscopies:

Q. So the record is clear, because you mentioned -- when you talked about as a pathologist having some clinical experience, that experience is uniquely involved in the procedure called colposcopy, as I understand it?

A. Correct.

Id. at 23:4-11. He has no clinical experience as a urologist, gynecologist, or urogynecologist:

Q. You are not a urologist by training?

A. Correct.

Q. You are not a urogynecologist by training?

A. Correct.

Q. You are not a gynecologist by training?

A. Correct.

Q. You do not and have not performed gynecologic surgery?

A. Correct.

Q. You do not and have not performed urologic surgery?

A. Correct.

Id. at 24:4-18. Dr. Wright has no clinical experience diagnosing or treating patients with stress urinary incontinence or pelvic organ prolapse:

Q. And other than that specific instance, it is fair to say that you are not in a practice that involves the diagnosis and treatment of stress urinary incontinence?

A. Correct.

Q. You are not in a practice and have never been in a practice that involved the diagnosis and treatment of female pelvic organ prolapse?

A. Correct.

Id. at 23:17-24:3. Dr. Wright has never examined, interviewed, or treated a patient suffering from POP or SUI:

Q. So you have never in your practice examined, interviewed, treated a woman for stress urinary incontinence or pelvic organ prolapse after they have been implanted with mesh?

A. Correct.

Id. at 47:6-10. He has never implanted or excised mesh from a mid-urethral sling or pelvic organ prolapse:

Q. Fair to say you have never implanted a mid-urethral sling?

A. Correct.

Q. Fair to say that you have never implanted a pelvic organ prolapse mesh?

A. Correct.

Q. Fair to say you have never excised portions of a mid-urethral sling?

A. Correct.

Q. Fair to say you have never excised portions of a pelvic organ prolapse mesh?

A. Correct.

Id. at 24:19-25:7. In short, Dr. Wright's expertise and experience in this litigation is limited to that of a pathologist:

Q. Any involvement that you would have in the issue of tissue response and polypropylene mesh would be within the specialty of pathology, correct?

A. Correct.

Q. So that is not a practice that involves seeing the patient in an office setting, correct?

A. Correct.

Q. It is not a practice that involves diagnosing a patient before a surgical procedure?

A. Correct.

Q. It is not a practice that involves making a clinical diagnosis on a patient after a procedure?

A. Correct.

Id. at 25:8-24.

3. Dr. Wright Should Be Precluded From Offering Opinions Beyond Pathology.

Despite Dr. Wright's lack of any applicable clinical experience as a treating physician, his report designates and attempts to offer opinions related to the causes of POP, treatment options for POP, and outcomes of those various treatments including the opinion that mesh repairs "have higher success rates than traditional surgery." Exhibit C at pp.1-2 (Expert Report of Thomas C. Wright, Jr., M.D.).¹ By Dr. Wright's own admission, his methodology as a pathologist leads to the conclusion that "histologic [i.e. pathologic] findings cannot be correlated with clinical complications....". Exhibit C at p.11; Exhibit A at 146:1-19. Likewise, Dr. Wright's histologic [i.e. pathologic] expertise cannot be correlated with opinions on clinical treatment of POP. Wright is a pathologist who has no "knowledge, skill, experience, training, or education" pertaining to urology, gynecology, and urogynecology. Fed.R.Evid.702. Dr. Wright lacks any clinical

¹ The remainder Dr. Wright's report properly focuses on his area of expertise (pathology), which includes tissue response to mesh implantation. Plaintiffs do not currently challenge Dr. Wright's qualifications as they relate to these pathological opinions of tissue response.

interaction with patients, and certainly no interaction to treat woman with POP in any clinical setting, whether pre-operatively, intra-operatively, or post-operatively. Therefore, Dr. Wright should be prohibited from offering any opinions, as identified in his report, regarding:

1. The incidence rate of POP in U.S. women;
2. The failure rate, quantitatively or in “relative” terms, of failure of traditional surgical repairs for POP;
3. A rationale for recurrent prolapse in POP patients;
4. Comparison of POP to abdominal hernia;
5. The clinical rationale for synthetic mesh products to treat POP;
6. The clinical success, failure, or comparative outcomes for mesh based repairs and non-mesh repairs. (Encompassed in Exhibit C at pp.1-2, “Reason for Using Implanted...”)

Dr. Wright is not qualified to offer opinions related to the causes of POP, treatment options for POP, and the success and/or failure rates of these POP treatments. All of the foregoing opinions will likely be proffered through Defendant’s urogynecology expert who is more qualified to offer said opinions. Therefore, these opinions should be excluded by the Court.

Conclusion

For the forgoing reasons, Dr. Wright’s proposed testimony and opinions outlined above are inadmissible and should be excluded.

DATED: April 20, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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